

AMENDED IN ASSEMBLY APRIL 29, 2003
AMENDED IN ASSEMBLY APRIL 22, 2003
AMENDED IN ASSEMBLY MARCH 25, 2003
AMENDED IN ASSEMBLY MARCH 5, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 103

Introduced by Assembly Members Reyes and Koretz
(Coauthors: Assembly Members Hancock and Lieber)
(Coauthors: Senators Chesbro, Romero, and Soto)

January 10, 2003

~~An act to add Sections 4168, 4169, and 4169.5 to the Business and Professions~~
An act to add Chapter 8 (commencing with Section 119400) to Part 15 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 103, as amended, Reyes. Pharmaceuticals: marketing activities.

~~Existing law, the Pharmacy Law, regulates wholesalers and manufacturers of dangerous drugs and makes the California State Board of Pharmacy responsible for administering and enforcing the provisions of that law. The Pharmacy Law makes a violation of its provisions punishable as a crime.~~

Under existing law, the State Department of Health Services generally regulates the safety, content, packaging, advertising, and use of various food and drug products.

This bill would prohibit any person or entity from engaging in the inappropriate marketing, as defined, of any dangerous drug or device to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California who is authorized to prescribe, dispense, or purchase dangerous drugs in this state.

Existing provisions of the Political Reform Act of 1974 prohibit specified state officials and candidates for state office from accepting gifts in excess of a specified amount.

This bill would define “inappropriate marketing” and would prohibit a pharmaceutical manufacturing company, as defined, from annually giving any gift, fee, payment, subsidy, or other economic benefit, except as specified, to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state that is more than the gift limit amount specified in existing regulations concerning gifts to state officials.

The bill would impose a civil penalty of \$10,000, enforceable by the department, the Attorney General, or a private party, for the violation of its requirements.

The bill, by specifying additional requirements under the Pharmacy Law, the violation of which is a crime, would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes no.

The people of the State of California do enact as follows:

- 1 ~~SECTION 1. Section 4168 is added to the Business and~~
- 2 ~~Professions Code, to read:~~
- 3 ~~4168. (a) It is unlawful for any person to engage in~~
- 4 ~~SECTION 1. Chapter 8 (commencing with Section 119400) is~~
- 5 ~~added to Part 15 of Division 104 of the Health and Safety Code,~~
- 6 ~~to read:~~
- 7

CHAPTER 8. DRUG MARKETING PRACTICES

119400. (a) No person or entity may engage in inappropriate marketing of any dangerous drug or device to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state.

(b) For purposes of this section, “inappropriate marketing” means any action intended to entice a physician or other medical provider to employ a dangerous drug or device in the treatment of a patient by offering any of the following:

(1) Cash payments to physicians of any kind.

(2) Gifts to physicians that are not directly related to the benefit of the patient or the practice of the physician related to the dangerous drug or device.

(3) Any cost for litigation in relation to the prescription of a dangerous drug or device.

(4) Travel, meals, or lodging for the physician unless they are associated with legitimate physician education.

~~SEC. 2.—Section 4169 is added to the Business and Professions Code, to read:~~

~~4169.—~~

119401. (a) A pharmaceutical manufacturing company shall not provide to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state any gift, fee, payment, subsidy, or other economic benefit in any calendar year in excess of the gift limit amount as described in Section 18940.2 of Title 2 of the California Code of Regulations, either directly or through its pharmaceutical marketers or wholesale distributors, in connection with detailing, promotional, or other marketing activities.

(b) A physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state shall not accept gifts, fees, payments, subsidies, or other economic benefits in any calendar year with a total value greater than the gift limit amount as described in Section 18940.2 of Title 2 of the California Code of Regulations, provided either directly by a pharmaceutical manufacturing company or through its

1 pharmaceutical marketers or wholesale distributors, in connection
2 with detailing, promotional, or other marketing activities.

3 (c) The following shall not be assessed as a gift as described in
4 subdivisions (a) and (b):

5 (1) A complimentary sample of a dangerous drug intended to
6 be furnished to a patient.

7 (2) The payment of reasonable compensation and
8 reimbursement of expenses in connection with a clinical trial of a
9 dangerous drug.

10 (3) Any economic benefit received through contracting for the
11 gross purchase of dangerous drugs or medical devices.

12 (d) The following definitions apply for purposes of this
13 ~~section~~ *chapter*:

14 (1) “Clinical trial” means an approved clinical trial conducted
15 in connection with a research study designed to answer specific
16 questions about vaccines, new therapies, or new ways of using
17 known treatments.

18 (2) “Dangerous drug” means any drug that is unsafe for
19 self-use and includes any of the following:

20 (A) Any drug that bears the legend “Caution: federal law
21 prohibits dispensing without prescription,” “Rx only,” or words
22 of similar import.

23 (B) (i) Any drug or device that, pursuant to federal or state law,
24 may be dispensed only with a prescription, or that is furnished
25 pursuant to Section 4006 *of the Business and Professions Code*.

26 (ii) “Dangerous drug” does not include labeled veterinary
27 drugs.

28 (3) (A) “Pharmaceutical manufacturing company” means an
29 entity that is engaged in the production, preparation, propagation,
30 compounding, conversion, or processing of dangerous drugs,
31 either directly or indirectly, by extraction from substances of
32 natural origin or independently by means of chemical synthesis or
33 by a combination of extraction and chemical synthesis.

34 (B) “Pharmaceutical manufacturing company” also means an
35 entity engaged in the packaging, repackaging, labeling, relabeling,
36 or distribution of dangerous drugs.

37 (4) “Pharmaceutical marketer” means a person who, while
38 employed by or under contract to represent a pharmaceutical
39 manufacturing company, engages in pharmaceutical detailing,
40 promotional, or other marketing activities of a dangerous drug in

1 this state to a physician, hospital, nursing home, pharmacist, health
2 benefit plan administrator, or any other person authorized to
3 prescribe, dispense, or purchase a dangerous drug.

4 ~~SEC. 3. Section 4169.5 is added to the Business and~~
5 ~~Professions Code, to read:~~

6 ~~4169.5.—~~

7 *119402.* (a) Any pharmaceutical manufacturing company,
8 physician, hospital, nursing home, pharmacist, health benefit plan
9 administrator, or any other person in California authorized to
10 prescribe, dispense, or purchase dangerous drugs in this state who
11 willfully and knowingly violates any provision of ~~Section 4168 or~~
12 ~~4169 this chapter~~ shall be liable for a civil penalty of not more than
13 ten thousand dollars (\$10,000) for each violation. Each violation
14 of these sections constitutes a separate offense for which the civil
15 penalty may be assessed. The prevailing plaintiff in the action shall
16 be awarded costs and reasonable attorney's fees in addition to the
17 civil penalty. *The State Department of Health Services, the*
18 *Attorney General, or a private party may bring a civil action to*
19 *enforce the provisions of this chapter.*

20 (b) Nothing in ~~Sections 4168 or 4169 this chapter~~ shall be
21 construed to impair or impede a licensing agency's authority under
22 any other provision of law.

23 ~~SEC. 4. No reimbursement is required by this act pursuant to~~
24 ~~Section 6 of Article XIII B of the California Constitution because~~
25 ~~the only costs that may be incurred by a local agency or school~~
26 ~~district will be incurred because this act creates a new crime or~~
27 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
28 ~~for a crime or infraction, within the meaning of Section 17556 of~~
29 ~~the Government Code, or changes the definition of a crime within~~
30 ~~the meaning of Section 6 of Article XIII B of the California~~
31 ~~Constitution.~~